

# VACCENTIS CORPORATE PRESENTATION

ZURICH, MARCH 2024



# WHO WE ARE: AN EXPERIENCED LEADERSHIP TEAM



Martin Munte CEO



**Dr. Ingrid Rauter** CMO and Head of R&D

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**Isabelle Lacher** CFO (Interim)



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AMGEN AstraZeneca



AMGEN

Baxter

SANDOZ A Novartis Division



**PUMAPHARM AG** PHARMACEUTICAL SPECIALTIES



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# **INVESTMENT THESIS PILLARS OF GROWTH**

#### Experienced new management team with proven track record

- VCC Medical division is developing clinically proven products, shown to maintain remission and alleviate disease
  - VCC-001 cancer vaccine Phase III data in Renal Cell Cancer has demonstrated clinical effect and was well tolerated, a disease with few current treatment options
  - VCC-001 cancer vaccine concept has significant potential in other solid tumour indications
- Exit strategy: Strategic Investor, Trade Sale or IPO in 3-5 years

### STRATEGIC FOCUS AND CREATING VALUE

### VCC-001 Regulatory Approval by 2029

### Autologous tumour vaccine technology platform «auto-tv»

 Vaccentis will focus entirely on developing immuno-oncology Vaccines utilising its autologous tumour vaccine technology platform «auto-tv»

#### **Extend pipeline**

• Creating value through an extended pipeline targeting cancers with high unmet needs

#### Manufacturing capabilities

• VCC-001 production for clinical trials and compassionate use guaranteed with established partner

# vcc medical



### UNMET MEDICAL NEED FOR RENAL CELL CANCER (RCC) PATIENTS POST-NEPHRECTOMY

#### Disease

- Post-nephrectomy of RCC limited treatment options with an acceptable safety profile available for both non-metastatic and metastatic RCC
- Currently only one adjuvant treatment approved for post-nephrectomy – Pembrolizumab
- Available treatment option in the adjuvant setting is associated with side effects and a high burden on the patient's quality of life
- Depending on risk group up to 50% of patients with RCC develop metastasis within 5 years post nephrectomy

### **Solution**

VCC-001 is an autologous tumour lysate vaccine based on the individual patient's tumour cells.

Used in Renal Cell Cancer (post-nephrectomy), VCC-001 shows:

- a highly specific immune response with proven efficacy
- a very favourable safety and side effects profile

VCC-001 demonstrated in a Phase III trial a significant progression free survival advantage.

Real world data were obtained in a large patient cohort and demonstrated an overall survival benefit even after 10 years.

In the real world study, patients with pT3 stage RCC revealed
5- and 10-year OS rates of 71.3% and 53.6% in the study group
and 65.4% and 36.2% in the control group (p = 0.022)

Jocham et al., The Lancet, Vol 363, 2004, Feb. 21: 597

May M et al: Ten-year survival analysis for renal carcinoma patients treated with an autologous tumour lysate vaccine in an adjuvant setting. Cancer Immunol Immunother. 2010 May;59(5):687-95



### EFFICACY (PFS) DEMONSTRATED IN PHASE III CLINICAL STUDY

### VCC-001 has already demonstrated significant clinical efficacy in Phase III with 553 patients

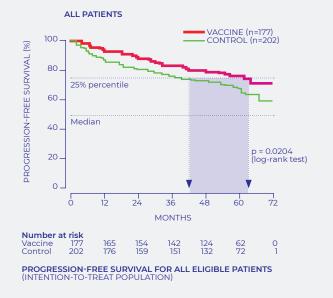
5-year (60 months) progression-free survival rates for patients at all tumour stages were 77.4% in the vaccine group and 67.8% in the control group (p=0.0204)

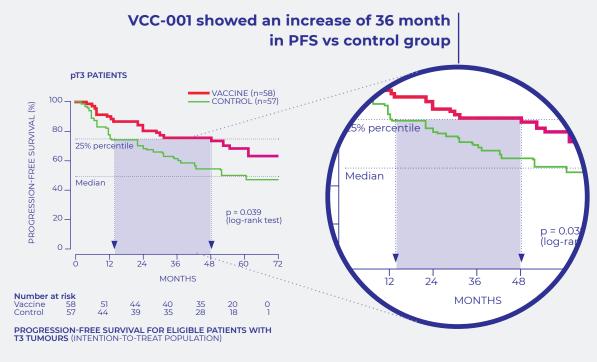
70-months progression-free survival rates were 72% in the vaccine group and 59.3% in the control group

### **PFS for all ELIGIBLE patients:**

### PFS for PT3 patients:

The time until 25% of patients had progressed was 63.2 months for patients in the vaccine group versus 42.1 months for those in the control group





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### VCC-001 DEMONSTRATED FAVORABLE SAFETY PROFILE IN PHASE III

- In the Intention to treat population 177 patients received A total of 1053 vaccine doses
- 12 vaccine-related adverse events of mild to moderate severity were noted in two patients
- The higher number of adverse events in the control groups can be accounted for by the higher number of patients with tumour progression in this group
- Clinically relevant abnormalities in blood chemistry variables were not recorded

	VACCINE GROUP N=276	<b>CONTROL GROUP</b> N=277	TOTAL N=553
Number of patients with adverse events (%)	108 (39%)	125 (45%)	233 (42%)
Number of patients with drug-related adverse events (%)	2 (1%)	-	2 (<1%)
Number of patients with serious adverse events (%)	64 (23%)	90 (32%)	154 (28%)
Number of adverse events	215	247	462
Number of drug- related adverse events	12	-	12
Number of serious adverse events	106	158	264
Adverse Events by frequency			
Progression, surgical intervention	45 (16%)	61 (22%)	106 (19%)
General disorders	33 (12%)	26 (9%)	59 (11%)
Neoplasm	13 (5%)	31 (11%)	44 (8%)
Urinary system disorders	15 (5%)	13 (5%)	28 (5%)
Gastrointestinal system	10 (4%)	11 (4%)	21 (4%)
Cardiovascular disease	5 (2%)	9( 3%)	14 (3%)
Metabolic and nutritional disorders	9 (3%)	6 (2%)	15 (3%)
Musculoskeletal system disorders	8 (3%)	7 (3%)	15 (3%)

Adverse events in 553 patients (safety population)



# VCC-001 CONCLUSION PHASE III

- A significantly reduced risk of tumour progression after radical nephrectomy using an autologous tumour cell lysate vaccination therapy
- The PFS 70 months after vaccination therapy was found to be 72% in the study group, while it was 59.3% in the control group (p = 0.0204)
- The incidence rate of side effects was minimal at <1%
- Quality of life was not impaired by the treatment itself or its application
- Autologous vaccination therapy can be recommended in patients with M0 RCC and a tumour diameter of >2.5 cm
- In a second survival analysis, a significantly increased OS was also reported for the vaccine group in the PP population



# **VCC-001 VERSUS COMPETITION**

# VCC-001: Potential differentiation and advantages over the licensed drug in RCC (adjuvant pembrolizumab)

	VCC-001	PEMBROLIZUMAB
EFFICACY	$\bullet \bullet \bullet \bullet \bigcirc$	$\bullet \bullet \bullet \circ \circ$
SAFETY/TOLERABILITY		$\bullet \circ \circ \circ \circ$
PHARMACOECONOMICS/PRICE		
PATENT VALIDATION		
EASE OF ADMINISTRATION		
TOTAL ASSESSMENT	$\bullet \bullet \bullet \bullet \bigcirc$	

VCC-001 is currently in development and not yet approved in the EU or USA. The evaluation is based on the clinical studies conducted and published. DISCLAIMER: NO COMPARISON BETWEEN THE TWO REFERENCED STUDIES IS NEITHER MADE NOR SHOULD COMPARABILITY BE INFERRED.

Adjuvant autologous renal tumour cell vaccine and risk of tumour progression in patients with renal-cell carcinoma after radical nephrectomy: phase III, randomised controlled trial; Jocham et al., Lancet, 2004 Feb 21;363(9409):594-9

Keytruda® – state of the art: Pembrolizumab versus placebo as post-nephrectomy adjuvant therapy for clear cell renal cell carcinoma (KEYNOTE-564): 30-month follow-up analysis of a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial, Lancet Oncol 2022; 23: 1133–44

Pembrolizumab yearly therapy costs depending on patient and indication: EU 125.000 – 145.000 Euro, US 150.000 – 180.000 USD



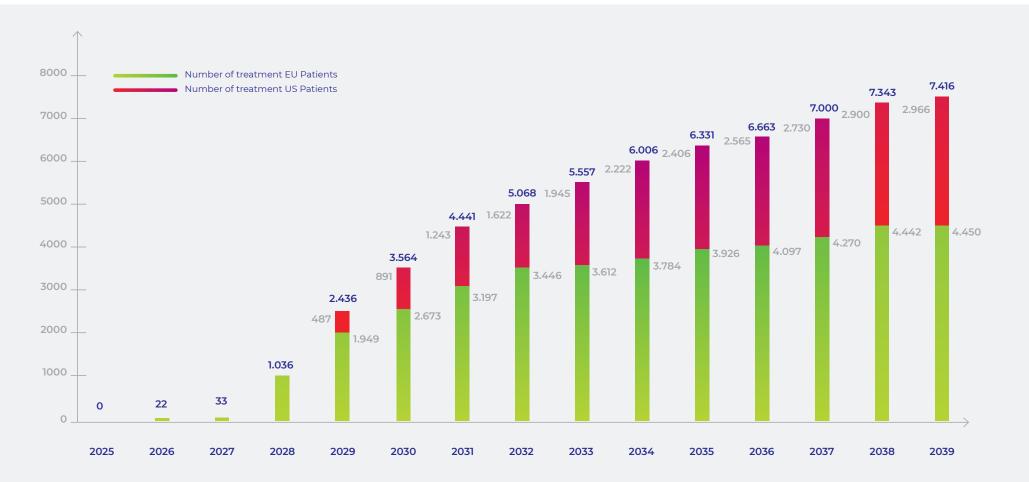
# TREATMENT ALGORHYTHM ccRCC

# Based on expert opinions from our KOL-advisors, 9.600 patients could potentially receive VCC-001 treatment immediately after regulatory approval in stage II and stage III adjuvant ccRCC\*

Staging/Clinical			Total Kidney cancer population p.a. in EU and USA	212.500
presentation	PT2	PT3	Number of Patients with Renal Cell Cancer [as a % of the total Kidney cancer population]	80%
Primary Treatment	Partial/Radical nephrectomy or Active surveillance	Partial/Radical nephrectomy	Number of Patients with Clear Renal Cell Cancer [as a % of the total Renal cancer population]	80%
	CT/Surveillance	Clear cell: CT/Surveillance	Number of Patients with receiving Nephrectomy [as a % of the total Clear Renal cancer population]	92%
		Number of Patients with T2 and T3 CRCC [as a % of the total Clear Renal cancer population]	25%	
	% of new T2 patient population with Nephrectomy 43%		Number of Patients with adjuvant clear	
Adjuvant	Number of patients in PT2 cancer 13.450	Number of patients in PT3 cancer 17.830	cell cancer T2 and T3 [new population]	31.280
Treatment	% receiving VCC-001 5%	% receiving VCC-001 50%		
••••••	% receiving Pembrolizumab 0%	% receiving Pembrolizumab 20%		
	% receiving other treatments 0%	% receiving other treatments 0%		
T T Z	% receiving no therapy 95%	% receiving no therapy 30%		
	Number of potential patients treated with VCC-001 672	Number of potential patients treated with VCC-001 8.915		
	Average treatment duration (months) 6	Average treatment duration (months) 6		

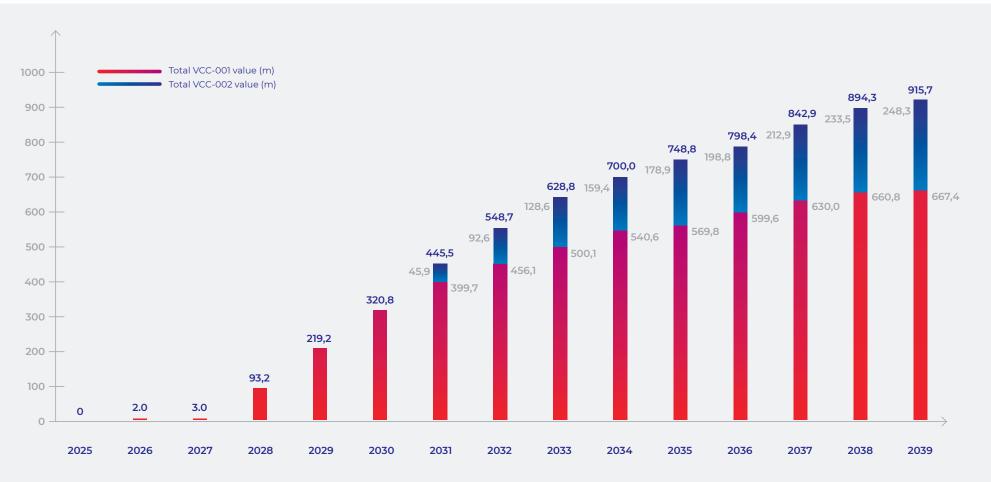


# THE PROJECTED PATIENTS IN EU AND US





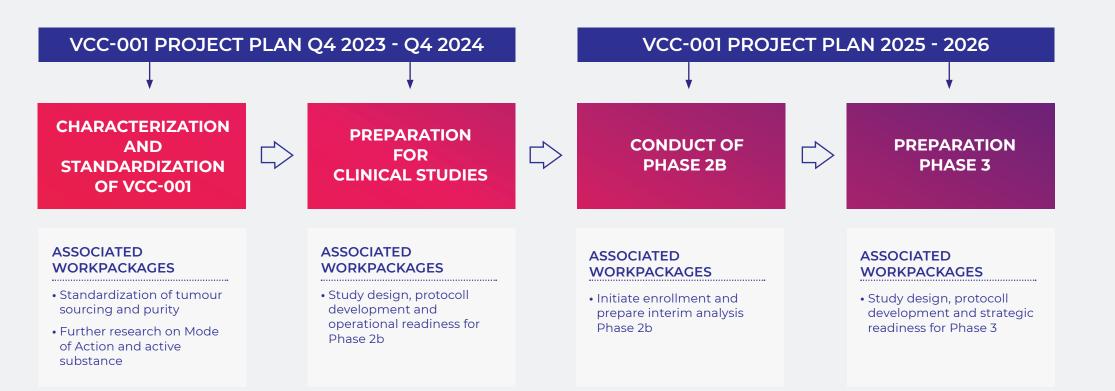
# THE PROJECTED SALES IN EU AND US



Price VCC-001: 150.000 – 180.000 US-Dollar/patient/year



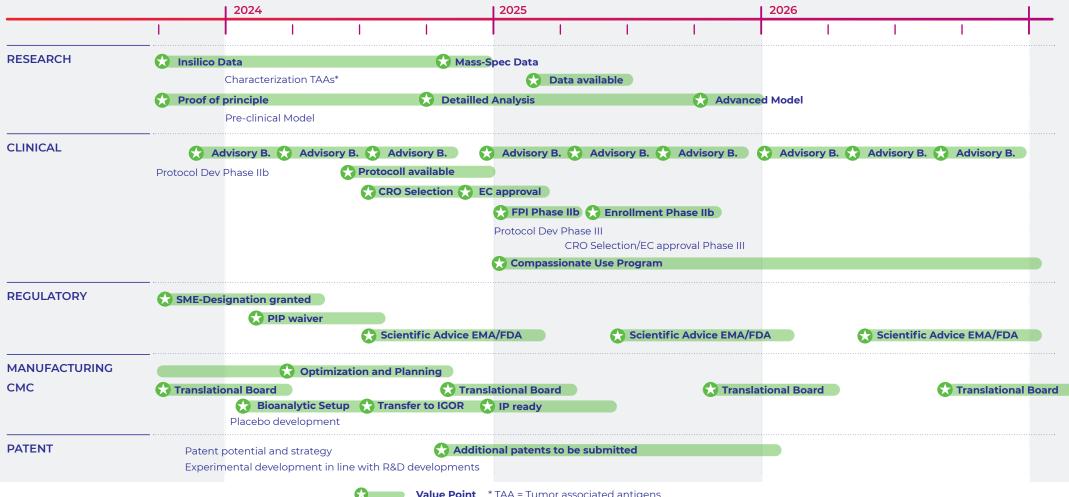
# VCC-001 – KEY WORK PACKAGES





### VACCENTIS DEVELOPMENT INVESTMENT CLINIC, **REGULATORY, CMC AND MANUFACTURING**

Vaccentis requires funding to pursue the clinical and regulatory development plan, including fully implementation and read out of a Phase IIb trial, to get to start a Phase III trial. For the financing of a Phase III trial a strategic partner is needed.



Value Point \* TAA = Tumor associated antigens



# THE WHY AND WHY NOW

# The Vaccentis products & pipeline have demonstrated clinical efficacy, they maintain remission and alleviate symptoms with favorable safety profile:

- VCC-001 showed a survival advantage in phase III clinical trials<sup>1</sup>
- The 5-year overall survival rates for patients with pT3 tumours were 71.3% in the vaccine group and 65.4% in the control group (p=0.022), the overall survival rates after 10 years were 53.6% and 36.2%, respectively<sup>2</sup>
- VCC-001 demonstrated highly favorable safety profile to pembrolizumab, the only licensed product in the adjuvant setting<sup>3</sup>
- VCC-001 is the foundation platform for further pipeline development based on autologous cancer vaccines
- The development plan for VCC-001 is based on existing advanced clinical data. Therefore, the possibility of obtaining marketing authorization is significantly higher than with a product candidate in preclinical or phase I
- The cost/benefit evaluation of Vaccentis therapies is very advantageous
- The time horizon for the concrete exit planning is 3 to 5 years

<sup>&</sup>lt;sup>1</sup> Doehn et al, second analysis, J Urol suppl 2006, vol 5, No 20, p. 286 Jocham et al.

<sup>&</sup>lt;sup>2</sup> May et al.: Adjuvante autologe Tumourvakzine beim Nierenzellkarzinom, Der Urologe 2009

<sup>&</sup>lt;sup>3</sup> No direct comparison



### USING THE PROCEEDS: TARGET OF CHF 35 MILLION R&D INVESTMENTS

THE INVESTMENTS 2024-2026	EXPECTED OUTCOME 2024, the standardization and characterization of VCC-001 will be established	
Vaccentis will invest <b>CHF 24 million</b> in clinical research to advance VCC-001		
Vaccentis will invest <b>CHF 5.5 million</b> to expand manufacturing and production matching the capacity for clinical trial supply and EU	2025, Vaccentis will start a Phase 2b trial to provide further data to enable preparation for Phase 3	
compassionate use program	2026, Vaccentis will generate first interim results on the Phase 2b	
Vaccentis will invest <b>CHF 3 million</b> to strengthen capabilities and extending work force through specialized clinical, regulatory and manufacturing staff	2026, VCC-001 may forecast first sales of <b>CHF 2 million</b> via the EU-Compassionate Use Program	
Vaccentis will invest <b>CHF 2.5 million</b> to extend the pipeline through	2028, anticipated EMA/FDA filing of VCC-001	
further preclinical research activities	2030, sales will exceed <b>CHF 320 million</b> through the launch of VCC-001	
Total required investment: CHF 35 million		

# **Information and Contact**

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